THE CENTER FOR FOOD SAFETY

Public Citizen 30 YEARS
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Re: food irradiation

Greetings,

On behalf of the many tens of thousands of consumer members of our two organizations, this is to request the opportunity to meet with you personally to discuss two major actions under consideration by FDA with respect to treatment of food by irradiation. First, FDA is considering five pending petitions to irradiate a much greater portion of the food supply, such as ready-to-eat foods, including many food items regulated by USDA Food Safety and Inspection Service. On May 16, our organizations filed comments opposing these petitions on grounds of serious safety issues stemming from scientific studies indicating that certain irradiated foods can have mutagenic and cytotoxic effects, in lab animals as well as humans.[1]

Second, FDA is considering changing the labeling regulation covering all irradiated foods. Suggestions from Congress have urged changing the wording of the label from "irradiated" to "cold pasteurized" or "electronically pasteurized." These suggestions contained in a conference report are, of course, not binding law and if followed would amount to interference in a matter clearly within FDA and FSIS's expertise and discretion.

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In its 1986 omnibus rulemaking addressing irradiation, FDA required that the food must be labeled to convey clearly that irradiation was used. FDA said that failure to disclose the material fact of irradiation would constitute misbranding. FDA also specifically rejected the suggestion that it allow a less descriptive label term like "picowave" instead of "radiation," on the basis that such a euphemism would not adequately inform consumers.[2] FDA stated it was "of the opinion that it is in the public interest for labels to bear a statement that is as descriptive of the process as possible." FDA's reasoning in 1986 is inconsistent with Congress's suggested change.

In addition, the USDA FSIS regulates labeling of irradiated meat and poultry. FSIS has declared part of its mission is to ensure that labels are truthful and not misleading, to protect consumers from misbranded meat and poultry. The FSIS guidelines for irradiation labeling plainly state:

> *At this time, labeling statements or claims for irradiated products that include the term "pasteurization" are misleading.*[3]

Suggestions from Congress aimed at enhancing the market share for irradiated food do not alter the fact that "pasteurization" has been found to mislead consumers by an agency with expertise. Pasteurization is a very different process from irradiation and confusing the two is deceptive. If FDA makes the contemplated change, the new label would directly contradict the FSIS guidelines, as well as the FSIS mission statement.[4]

Moreover, the contemplated change would contradict the internationally declared position of the U.S. government on deceptive labeling. In a discussion paper submitted to the April 30-May 4, 2001 meeting of the Codex Alimentarius Committee on Food Labelling in Ottawa, the U.S. position on the topic of "Confusion-Based Misleadingness" was stated as:

> *Consumers may be misled by the use of confusing language, symbols, or images on packages. Confusion often occurs because a promotional communication uses a word, phrase, symbol, or image that is similar to a more familiar word, phrase, symbol or image, but that does not have a similar meaning. Such confusion is likely to cause consumers to misperceive or to miscomprehend the communication.*[5]

This U.S. position stands against the suggested use of "pasteurized" rather than "irradiated" because the suggestion uses a familiar, but inaccurate, word. Many consumers will be misled.

Under case law interpreting the Federal Drug, Food, and Cosmetics Act, "A food shall be deemed to be misbranded if its labeling is false or misleading in any particular."[6] The Supreme Court in *U.S. v. 95 Barrels of Apple Cider*,[7] deemed a label to be misleading if it misrepresents the article in any way. According to that case, the Act "condemns every statement, design and device which may mislead or deceive".[8] Courts have followed this precedent in deciding whether a label is adequate. The legal test is not the effect of the label on a "reasonable consumer," rather its effect upon even "the ignorant, the unthinking and the credulous" customer.[9] If FDA and FSIS allow use of the term "pasteurized" on the label, the agencies

would violate the FDCA as interpreted by the Supreme Court because neither the typical nor the credulous consumer will have any way of knowing the food was irradiated. Another Federal Court opinion warns that the FDCA's misbranding prohibition "does not provide for much flexibility in interpretation."[10]

Public opinion mirrors previous agency guidelines and Federal Court guidance on this topic. According to an objective survey in 1999, the public thinks that euphemistic language like "cold pasteurization" is a bad idea, preferring the current "irradiated" label by a margin of about 6 to 1.[11] Indeed, when FDA asked for public comment on this very topic, the overwhelming weight of the comments favored the current terminology. According to the report prepared by FDA's own consultant on the public's views, 78.7 percent of respondents who addressed the label terminology stated they wanted the current labeling requirements maintained, and 19.5 percent stated they wanted to strengthen the labeling requirements to include foods with irradiated ingredients. (Currently, multi-ingredient foods that contain irradiated meat ingredients must be labeled as such; there is no such requirement, however, for multi-ingredient foods that contain non-meat ingredients that have been irradiated.) In total then, 98.2 percent of respondents said they wanted the current labeling requirements maintained or strengthened.[12] A *de minimis* number of commenters – less than 1.1 percent – preferred the word "pasteurized."

Because there is such overwhelming evidence against changing the labeling terminology, it would be arbitrary and capricious for FDA to do so. Indeed, it would be the first case in which Congress – merely through conference report language – ordered a deliberately misleading label to be used on a product in place of a truthful and informative label, one consumers strongly prefer. It would be a bad precedent and a subterfuge of the FDCA, a major thrust of which is to allow relatively unregulated markets to work, but only so long as products do not carry misleading labels.

We urge FDA to refrain from making such a change and request the opportunity to discuss these food safety and labeling matters further. Please contact Peter Jenkins of CFS (tel: 202.547.9359 x13; email: peterjenkins@icta.org) in order to arrange a meeting with us at your convenience.

Sincerely,

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Cc: Secretary Ann Veneman, USDA
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[1] Further copies of these comments are available on request or they can be accessed on the CFS website at http://www.centerforfoodsafety.org/li.html.

[2] 51 FR 13376, at p. 13390.

[3] U.S.D.A, *Office of Policy, Program Development and Evaluation, Labeling and Consumer Protection Staff* http://www.fsis.usda.gov/OPPDE/larc/Irradiation_Q_&A.htm (accessed May 22, 2001).

[4] U.S.D.A, *Office of Policy, Program Development and Evaluation, Labeling and Consumer Protection Staff* http://www.fsis.usda.gov/OPPDE/larc/index.htm (accessed May 22, 2001).

[5] "Discussion Paper on Misleading Food Labels: Prepared by the United States." Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling, Twenty-ninth Session, Ottawa, Canada, 30 April - 4 May 2001. Prepared by Christine J. Lewis, Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA.

[6] 21 U.S.C. § 343 (a).

[7] *U.S. v. 95 Barrels Apple Cider Vinegar*, 265 U.S. 438 (1924).

[8] *U.S. v. 95 Barrels Apple Cider Vinegar*, 265 U.S. at 442.

[9] *U.S. v. Strauss*, 999 F.2d 692, 696 (1993), (quoting *U.S. v. An Article.... Sudden Change*, 409 F.2d 734, 740 (2d Cir. 1969)).

[10] *U.S. v. An Article of Food Consisting of 432 Cartons, More or Less...*, 292 F.Supp. 839, 840 (USDC SDNY 1968).

[11] Bruskin/Goldring Research Survey of more than 1,000 adults conducted in 1999. Commissioned by Center for Science in the Public Interest and the American Association of Retired Persons.

[12] Memorandum dated Mar. 14, 2001, from A. Benjamin, R. Morin, and B. Jones, ICF Consulting, to Dr. William Trotter, FDA, and Jéanette Glover Glew, Project Officer, FDA, *Final Report: FDA's Proposed Revisions to the Labeling Requirements for Irradiated Foods, Overview of Public Comments*, pp. 19-23.